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UNITED STATES SURGICAL, A DIVISION OF TYCO HEALTHCARE GROUP LP				TOY, ALEX B	
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				3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on October 16, 2006. The objection to claim 14 is withdrawn. All previous prior art rejections are maintained. In addition, new grounds of rejection are made.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Rigby (U.S. Pat. No. 5,254,117).

Regarding claim 1, Rigby discloses an electrosurgical pencil, comprising: a housing 42 (Fig. 1);

an electrode 26 supported within the housing and extending distally from the housing (Fig. 1), the electrode being connected 14 to a source of electrosurgical energy (Fig. 1);

an activation button 22 configured and adapted to selectively supply electrosurgical energy to the electrode upon actuation thereof (Fig. 1); and

an aspirating/irrigating system integrally formed with the housing, wherein the aspirating/irrigating system is configured and adapted to manually perform at least one

of delivering a quantity of fluid to a target surgical site and withdrawing a quantity of fluid from the target surgical site (col. 5, In. 24-40 and Figs. 1 and 6).

Regarding claim 2, Rigby discloses the electrosurgical pencil according to claim 1, wherein the aspirating/irrigating system includes a resilient handle 42 (col. 5, In. 56-58), the resilient handle defining at least one chamber therein (Fig. 6).

Regarding claim 3, Rigby discloses the electrosurgical pencil according to claims 1 and 2, wherein the aspirating/irrigating system further includes a fluid passage (12, 39, 41) extending between the at least one chamber of the resilient handle and at least one aperture (the distal opening) formed in a distal end of the housing 42 (Fig. 6).

Regarding claim 4, Rigby discloses the electrosurgical pencil according to claims 1-3, wherein a quantity of fluid is contained within the at least one chamber of the resilient handle (Fig. 6). Since irrigation hoses 39, 41 deliver fluid to the distal tip (col. 5, ln. 24-40), a quantity of fluid is inherently contained in the hoses that is also contained within the chamber the handle.

Claims 1-6, 21, 27-28, and 30-31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wood (U.S. PGPub 2002/0151886 A1).

Regarding claim 1, Wood discloses an electrosurgical pencil, comprising: a housing 20, 61 (Figs. 1 and 3A);

an electrode 62 supported within the housing and extending distally from the housing 61 (Fig. 3A), the electrode being connected to a source of electrosurgical energy (pg. 6, ¶ 64);

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an activation button configured and adapted to selectively supply electrosurgical energy to the electrode upon actuation thereof (pg. 3-4, ¶ 35 and 44); and

an aspirating/irrigating system integrally formed with the housing, wherein the aspirating/irrigating system is configured and adapted to manually perform at least one of delivering a quantity of fluid to a target surgical site and withdrawing a quantity of fluid from the target surgical site (pg. 4, ¶ 42, pg. 6, ¶ 64, and Figs. 1 and 3A).

Since the power delivered to the electrode is controlled by a microprocessor, the device of Wood obviously, if not inherently, comprises an activation button as claimed, even if the button merely comprises a button to turn on and activate the microprocessor.

Regarding claim 2, Wood discloses the electrosurgical pencil according to claim 1, wherein the aspirating/irrigating system includes a resilient handle 25, the resilient handle defining at least one chamber therein.

Since the plunger and tube portion of the syringe are both designed to be held and operated by hand, the entire syringe comprises a handle. In addition, applicant has not specifically defined "handle". Therefore, the broadest reasonable interpretation of handle is used. The chamber is formed by the insertion of the plunger into the tube. Finally, it is well-known in the art that syringes are commonly made of plastic which is inherently resilient. Therefore, the syringe of Wood is obviously, if not inherently, resilient.

Regarding claim 3, Wood discloses the electrosurgical pencil according to claims 1 and 2, wherein the aspirating/irrigating system further includes a fluid passage (the inner lumen 66 of electrode 62) extending between the at least one chamber of the

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resilient handle and at least one aperture (the distal opening) formed in a distal end of the housing 61 (pg. 6, ¶ 64).

Regarding claim 4, Wood discloses the electrosurgical pencil according to claims 1-3, wherein a quantity of fluid is contained within the at least one chamber of the resilient handle (pg. 6, ¶ 64).

Regarding claim 5, Wood discloses the electrosurgical pencil according to claims 1-4, wherein the resilient handle has an expanded condition and is compressible to a non-expanded condition, wherein compression of the resilient handle causes the quantity of fluid contained in the at least one chamber of the resilient handle to be urged through the fluid passage and out of the at least one aperture formed in the distal end of the housing (pg. 6, ¶ 64).

The expanded condition is when the syringe plunger is extended, and the nonexpanded condition is when the plunger is compressed into the syringe tube.

Regarding claim 6. Wood discloses the electrosurgical pencil according to claims 1-5, wherein when the resilient handle is allowed to return to its expanded condition from the non-expanded condition, fluid is drawn into the at least one chamber of the resilient handle through the fluid passage and in through the at least one aperture formed in the distal end of the housing.

The device of Wood is inherently capable of performing the intended use of drawing in fluid as claimed.

Regarding claim 21, see the preceding rejections of claims 1-5.

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Regarding claim 27, see the preceding rejections of claims 1-5 and the following rejection of claim 30.

Regarding claim 28, see the preceding rejections of claims 3 and 27.

Regarding claims 30-31, see the preceding rejections of claims 1-3. In addition, the resilient handle of Wood comprising the syringe 25 is configured such that compression of said handle causes the delivery of a quantity of fluid to a target surgical site and expansion of said handle to an uncompressed condition causes the withdrawal of a quantity of fluid from a target surgical site.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wood (U.S. PGPub 2002/0151886 A1) in view of Spitz (U.S. Pat. No. 6,352,544 B1).

Regarding claim 14, Wood discloses the electrosurgical pencil according to claims 1 and 2. The claim differs from Wood in calling for the resilient handle to be fabricated from rubber. Spitz, however, teaches using a rubber bulb or a syringe as obvious interchangeable means for injecting fluid into a catheter lumen (col. 5, In. 56-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a rubber bulb instead of a syringe to inject fluid with the device of Wood in view of the teaching of Spitz that a rubber bulb and a syringe are obvious interchangeable means for injecting fluid into a catheter lumen. Thus, the resilient handle of Wood in view of Spitz is fabricated from rubber.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wood (U.S. PGPub 2002/0151886 A1) in view of Abele (U.S. Pat. No. 5,190,541)

Regarding claim 29, Wood discloses the method of claims 27 and 28. The claim differs from Wood in calling for the step of:

partially compressing the handle and placing the aperture in a quantity of fluid and allowing the handle to expand to withdraw fluid into the at least one chamber.

Abele, however, discloses an analogous electrosurgical device with a separate suction syringe 26 in addition to a fluid delivery syringe 28, wherein the step as claimed is performed to clean and remove blood from the surgical area (col. 7, ln. 14-25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an additional suction syringe and performed the step as claimed with the device of Wood in view of the teaching of Abele in order to clean and remove blood from the surgical area.

Response to Arguments

Applicant's arguments with respect to the pending claims have been fully considered but they are not persuasive.

Regarding independent claim 1:

Applicant argues that the aspirating/irrigating system of Wood is not integrally formed with the housing as claimed. In response to this argument, it has been held that the term "integral" is sufficiently broad to embrace constructions united by such means as fastening and welding. *In re Hotte*, 177 USPQ 326, 328 (CCPA 1973).

In addition, even if applicant traverses this holding, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the aspirating/irrigating system of Wood integrally formed with the housing as claimed, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

To define over Wood and Rigby, it is suggested that applicant consider amending claim 1 to recite that a fluid supply source is located within the housing of the electrosurgical pencil.

Regarding independent claim 21:

Applicant argues that the aspirating/irrigating system of Wood is not self-contained. In making this argument, applicant asserts that being of "one unitary element" is the criterion for being self-contained (pg. 13, ln. 1-4). In accordance with this criterion, the examiner maintains that the aspirating/irrigating system of Wood comprising syringe 25 is clearly one unitary element.

Applicant further argues that syringe 25 is completely separate from catheter 20 (
the electrosurgical pencil) (pg. 13, ln. 5-9). The *American Heritage Dictionary*, however,
defines "self-contained" as "constituting a complete and independent unit in and of itself"
(*The American Heritage® Dictionary of the English Language, Fourth Edition*. Houghton
Mifflin Company, 2004). Therefore, that applicant argues that syringe 25 is completely
separate from catheter 20 appears to actually be in accordance with the definition of
"self-contained" and strengthen the examiner's position.

As with claim 1, it is suggested that applicant consider amending claim 21 to recite that a fluid supply source is located within the housing of the electrosurgical pencil to define over Wood and Rigby.

Regarding independent claims 27 and 30:

Applicant argues that Wood does not disclose a resilient handle. Applicant acknowledges that it would have been obvious, if not inherent, for the syringe to comprise plastic. Applicant, however, maintains that the syringe of Wood must comprise a non-resilient, hard plastic because otherwise, there would be no need for a plunger (pg. 14, ln. 9-15).

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In response to this argument, the examiner maintains that resilient is a relative term and that any hard plastic is resilient compared to a material like steel. In addition, the examiner maintains that the walls of a syringe tube are inherently relatively thin enough that if enough force is applied, the tube would flex and then spring back to the original form when released in a resilient manner.

Applicant further argues that the body or cylinder of the syringe of Wood cannot itself be compressed in order to deliver fluid and cannot itself be allowed to expand in order to withdraw any quantity of fluid and that a plunger must be used in cooperation with the body to manually deliver or withdraw any fluid (pg. 14, ln. 16-22).

In response to this argument, the examiner maintains that the resilient handle of Wood comprises the entire syringe tube and plunger. Therefore, the syringe handle of Wood is inherently "configured and adapted to deliver a quantity of fluid contained in the handle to a target surgical site when the handle is compressed (i.e. the syringe handle compresses and delivers fluid when the plunger is pushed into the tube) and withdraw a quantity of fluid from the target surgical site when the handle is allowed to expand" (i.e. the syringe handle expands and withdraws fluid when the plunger is withdrawn from the tube).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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AT AT 11/30/06

> MICHAEL PEFFLEY PRIMARY EXAMINER

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